

Attorney Docket No. P63187US2
Application No. 10/722,467

Remarks/Arguments:

Applicants wish to thank Supervisory Patent Examiner (SPE) Sreenivasan Padmanabhan and Primary Examiner Yong S. Chong, for the courteous consideration rendered applicants' representative during an interview at the PTO on 6 July 2009 and during a telephone interview on 21 July 2009. The substance of the interviews concerned the final rejection under §103(a), the references relied on in the rejection, and the rejected claims.

Claims 12-22 are pending.

Claims 1-11 were cancelled without prejudice or disclaimer.

Claims 12-21 were previously presented.

New claim 22 contains the subject matter of claim 12 further limited to "without any increase in bone density being detectable by radiological examination following treatment," as described at page 7 of the application as filed.

The presently claimed invention is most broadly directed to *veterinary use of specific bisphosphonic acid derivatives to treat osteoarthritis-induced lameness.*

Claims 12-21 were provisionally rejected for alleged obviousness-type double patenting over copending U.S. patent application no. 11/406,296. In that the rejection is "provisional," no response appears to be presently necessary. Should the rejection be made non-provisional—in a future action—the necessary response will be provided. *See MPEP 804(I)(B)(1).*

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Claims 12-21 were rejected rejection for alleged obviousness, under 35 USC 103(a), over U.S. 5,488,041 (Barbier), of record, in view of U.S. 3,637,641 (Huber), newly cited. Reconsideration is requested.

The rejected claims—most broadly—are directed to *veterinary use of specific bisphosphonic acid derivatives to treat osteoarthritis-induced lameness* (as indicated above). According to the statement of rejection (final Office Action, page 5) (emphasis added),

the limitation "caused by osteoarthritis" is given little patentable weight since the disorder, lameness, is still clinically the same no matter what the etiology or origin of the disorder is.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have administered a bisphosphonic acid derivative, for example 4-chlorophenyl thiomethylenebisphosphonic acid, as taught by Barbier et al. to treat lameness in a horse suffering from osteoarthritis as taught by Huber et al.

A person of ordinary skill in the art would have been motivated to administer a bisphosphonic acid derivative, for example 4-chlorophenyl thiomethylenebisphosphonic acid, as taught by Barbier et al. to treat lameness in a horse suffering from osteoarthritis as taught by Huber et al. because: (1) Barbier et al. teach broadly that bisphosphonic acid derivatives are useful for treating bone disorders; and (2) Huber et al. teach that bony exostosis, also known as osteoarthritis, is a common bone disorder in horses characterized by lameness and difficulty in locomotion or limping. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating lameness in horses suffering from osteoarthritis by administering a bisphosphonic acid derivative, such as 4-chlorophenyl thiomethylenebisphosphonic acid.

With all due respect, the rejection—as shown by its supporting arguments—relies on clearly erroneous findings of fact and, furthermore, is legally in error.

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I. Barbier and Huber cannot be combined: they "teach away" from and "destroy" each other's inventions

Submitted herewith is the evidentiary (Rule 132) declaration of co-inventor Dominique Thibaud ("the Rule 132 declaration"). In the Rule 132 declaration, Dr. Thibaud "as an expert in the field of the invention" explains how Barbier and Huber are incompatible with one another: Essentially, Barbier is directed to promoting bone growth; whereas, Huber is directed to inhibiting bone growth.

For example, as set forth in the Rule 132 declaration (emphasis original):

As taught by Barbier (column 1, lines 8-15) ... bisphosphonic acid derivatives promote bone formation. ... Huber (column 4, lines 1-4) teaches "with continued [orgotein] treatment ... at least some of the structural abnormalities associated with the [bony exostosis] condition" are lessened.

So, ... it would not make sense to a person skilled in the art "to administer a bisphosphonic acid derivative"—which promotes bone formation—"as taught by Barbier et al. to treat lameness in a horse ... as taught by Huber et al."—which requires lessening bone formation ... consequently, administering a bisphosphonic acid derivative to a non-human animal suffering from bony exostosis—instead of orgotein—as taught by Huber, would exacerbate the bony-exostosis-induced "lameness," the "clinical improvement" of which is an objective according to Huber (column 3, lines 63-64).

Huber clearly shows that "orgotein" is useful in treating bony exostosis precisely because it lessens the growth of bone. As exemplified in Huber Examples 1, 2, 4, 7, 8, and 14, X-ray examination post orgotein administration revealed reduced size or shape of bony exostosis. Based on Barbier's teachings, bisphosphonic acid derivatives do exactly the opposite of what Huber obtains—by using orgotein.

It should also be pointed out that, besides having functionally dissimilar properties, orgotein—a macromolecular protein—is structurally dissimilar, completely, to the simple, small molecules that constitute the bisphosphonic acid derivatives at issue.

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Accordingly, Barbier—using bisphosphonic acid derivatives to promote bone formation—and Huber—using orgotein to inhibit bone formation—teach away from one another; and, so, one skilled in the art would have had no motivation to combine them—rendering the obviousness finding incorrect.

To establish a *prima facie* case of obviousness . . . [one] must show "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." . . . There is no suggestion to combine, however, if a reference teaches away from its combination with another source.

Tec Air, Inc., v. Denso Manufacturing Michigan Inc., 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (emphasis added) (internal citations omitted). If the first of two cited references "teach[es] away from [the second reference], then that finding alone can defeat [the alleged] obviousness claim." *Winner Int'l. Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587 (Fed. Cir. 2000), *cert. denied*, 530 U.S. 1238 (2000). Since Barbier teaches away from Huber—and *vice versa*—the rejection for obviousness is defeated. *Winner Int'l. Royalty Corp.*, 53 USPQ2d at 1587.

Moreover, Barbier—using bisphosphonic acid derivatives to promote bone formation—and Huber—using orgotein to inhibit bone formation—if combined, would necessarily result in destroying the invention on which one of the inventions is based: Using (Barbier's) bisphosphonic acid derivatives in Huber would destroy the "lessening" of bone formation on which Huber is based and using (Huber's) orgotein in Barbier would destroy the "bone forming" invention on which Barbier is based; thereby rendering the obviousness finding incorrect.

If when combined, the references would produce a seemingly inoperative device, then they teach away from their combination. . . . [There is] no suggestion to modify

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a prior art device where the modification would render the device inoperable for its intended purpose.

Tec Air, Inc., 52 USPQ2d at 1298 (emphasis added) (internal citations omitted). In an obviousness analysis, a reference can not be combined with another reference in such a way that destroys the invention on which one of the references is based. *Ex parte Hartmann*, 186 USPQ 366 (POBdApp 1974). References cannot be combined to show obviousness when the combination would produce a "seemingly inoperative device." *In re Sponnoble*, 160 USPQ 237, 244 (CCPA 1969). *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose).

Note is taken of the aforesaid PTO allegation "Barbier et al. teach broadly that bisphosphonic acid derivatives are useful for treating bone disorders." The Rule 132 declaration clearly explains how Barbier does not "broadly" teach "treating bone disorders." On the contrary, Barbier's teachings are limited to the treatment of fractures—by promoting bone repair; and, it is this use of bisphosphonic acid derivatives to repair, i.e., grow, bone, which teaches away from Huber (as explained above).

The PTO must take into account the totality of the Huber and Barbier teachings, which evidences how the references "teach away" from and "destroy" each other's invention, as explained above. The PTO "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

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It is impermissible within the framework of §103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

In re Hedges, 228 USPQ 685, 687 (Fed. Cir. 1986). Teachings of the prior art must be taken as a whole in an obviousness analysis. *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 21 USPQ2d 1053 (Fed. Cir. 1991).

In the context of a rejection for obviousness under §103, the "Examiner bears [both] the initial burden . . . of presenting a *prima facie* case of unpatentability" and "the ultimate burden of persuasion on the issue." *In re Oetiker*, 24 USPQ 1443, 1444 and 1447 (Fed. Cir. 1992) "The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant references. . . . Indeed, the teachings of the references can be combined only if there is some suggestion or incentive to do so." *Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (BPA&I 1992) (emphasis, added). Since Barbier and Huber teach away from one another (as explained above), the requisite motivation to combine them—the "suggestion or incentive to do so"—is lacking, rendering the rejection based on the cited references untenable. *Obukowicz*, 27 USPQ2d at 106. *Tec Air, Inc.*, 52 USPQ2d at 1298.

In view of the foregoing remarks, the rejection of claims under §103(a), based on the combined teachings of Barbier and Huber, is overcome. Withdrawal of the rejection appears to be in order.

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II. Barbier and Huber fail to satisfy "all limitations rule"

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

The rejected claims are limited to treating "a non-human animal . . . not suffering from fractures" (emphasis added), which limitation must be met by the cited references to establish obviousness under §103(a). *Royka, supra*. *Wilson, supra*. *Murphy, supra*. *Thrift, supra*. Barbier's teachings, on the other hand, are limited to the treatment of fractures, and Huber provides no teaching or suggestion that cures this fatal deficiency in Barbier, which the PTO cannot ignore in comparing the claims with the cited references. *Hedges, supra*. *Ryko Manufacturing Co., supra*.

The statement of rejection does include a detailed description of what allegedly occurs, morphologically and structurally, as a result of the treatments disclosed in Barbier and Huber (Office Action, page 4, line 7, through page 5, line 17). Nevertheless, neither these allegations nor the Barbier and Huber references, themselves, provide the requisite motivation for—and actually teach away from (as explained above)—their combination. Although the allegations "go a long way

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towards providing a scientific explanation for [allegedly] *what happened* when ... [performing] the claimed combination of process steps ... the references themselves fall far short of the 'motivation' or 'suggestion' to assemble their teachings into a viable process." *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (BPA&I 1993).

In view of the foregoing remarks—regarding failure to satisfy the "all limitations" rule—the rejection of claims under §103(a), based on the combined teachings of Barbier and Huber, is overcome. Withdrawal of the rejection appears to be in order.

III. Limitation "caused by osteoarthritis" impermissibly discounted

As set forth above, the statement of rejection alleges (emphasis added)

the limitation "caused by osteoarthritis" is given little patentable weight since the disorder, lameness, is still clinically the same no matter what the etiology or origin of the disorder is.

The statement of rejection fails to provide any evidence, whatsoever, that supports the allegation, which renders the rejection untenable—for failing to give the limitation "patentable weight."

"It is facts which must support the legal conclusion of obviousness." *Ex parte Crissy*, 201 USPQ 689, 695 (POBdApp 1976).

The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.

In re Warner, 154 USPQ 173, 178 (CCPA 1967) (emphasis original). An argument by the USPTO is "not prior art." *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

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Accordingly, the allegation being unsupported, if the rejection is not withdrawn, applicant calls for the supporting affidavit of the examiner in accordance with 37 CFR 1.104(d)(2) [MPEP707.05], i.e.:

(d) Citation of references. . . .

(2) When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.

In view of the foregoing remarks—regarding the unsupported allegation—the rejection of claims under §103(a), based on the combined teachings of Barbier and Huber, is overcome—absent the examiner's supporting affidavit under Rule 104. Withdrawal of the rejection appears to be in order.

IV. Claim 22 is independently patentable

New claim 22 limits the subject matter of the rejected claims "without any increase in bone density being detectable by radiological examination following treatment" (as explained above). An inherent feature in Barbier is an increase in bone density after treatment—necessarily resulting from the bone repair/growth of the disclosed treatment. Huber provides nothing that cures this fatal deficiency in Barbier, i.e., Barbier cannot be combined with Huber in any way that prevents the increase in bone density, since to do so would destroy the invention on which Barbier is based. *Tec Air, Inc.*, 52 USPQ2d at 1298. *Hartmann, supra*. *Sponnoble*, 160 USPQ at 244. *Gordon*, 221 USPQ at 1127. *Ex parte Hartmann*, 186 USPQ 366 (POBdApp 1974) (In an obviousness analysis,

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a reference can not be combined with another reference in such a way that destroys the invention on which one of the references is based).

Accordingly, since "the cited references do not support each limitation of [the] claim," applying the obviousness rejection—based on the combined teachings of Barbier and Huber—would be "inadequate on its face." *Thrift*, 63 USPQ2d at 2008.

Favorable action is requested.

Respectfully submitted,



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